



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

NOV 19 1997 0562 '98 MAR 24 P2:43

Mr. Gordon M. Walker
Regulatory Counsel
Nature's Way
10 Mountain Springs Parkway
Springville, Utah 84663

Dear Mr. Walker:

This is in response to your letter of October 13, 1997 to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that Nature's Way is making the following claim for a product containing cranberry:

"Promotes urinary tract health. Nature's Way Cranberry (*Vaccinium macrocarpon*) helps maintain a healthy urinary tract by inhibiting the adhesion of *E. Coli* bacteria to the lining of the bladder."

Section 403(r)(6) of the act makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, cure, or mitigate disease, namely, bladder infections caused by the adhesion of pathogenic strains of *E. coli* to the bladder wall. Because the adhesion to the bladder wall of non-pathogenic strains of *E. coli* would not result in disease, only the inhibition of adhesion of pathogenic strains of microorganisms would be expected to contribute positively to the urinary tract health of the person using the product. The claim made for this product does not meet the requirements of section 403(r)(6) of the act. This claim suggests that this product is intended for use as a drug within the meaning of section 201(g)(1)(B) of the act, and that it is subject to regulation under the drug provisions of the act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

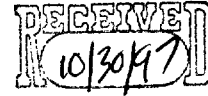
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October 13, 1997

Linda S. Kahl, Ph.D.
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" St. S.W. (HFS-450)
Washington, D.C. 20204



Dear Dr. Kahl:

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994, Nature's Way Products, Inc. wishes to notify the Food and Drug Administration that it has within the past 30 days, commenced marketing a dietary supplement which bears a statement of nutritional support.

The dietary supplement for which the statement is made is Cranberry. The dietary ingredient that is the subject of the statement is Cranberry. The statement of nutritional support reads as follows:

"Promotes urinary tract health. Nature's Way Cranberry (*Vaccinium macrocarpon*) helps maintain a healthy urinary tract by inhibiting the adhesion of *E. Coli* bacteria to the lining of the bladder."

This statement is accompanied by the required disclaimer which is prominently displayed in bold-faced type.

This statement of nutritional support is based on data which renders these statements substantiated, truthful and non-misleading.

Sincerely,

NATURE'S WAY PRODUCTS, INC.

Gordon M. Walker
Regulatory Counsel

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